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THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application: Alan J. MAGILL et al.

Serial No.: 09/975,020

Group Art Unit: 1646

Filed: 12 October 2001

Examiner: To Be Assigned

Docket. No.: P66822US0 (WRAIR 98-40/46)

For: MICROFLUIDIZED LEISHMANIA LYSATE AND METHODS OF MAKING AND USING THEREOF

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Listed on the accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. § 1.56, 1.97 and 1.98. Copies of references 1, 2, and AA-AR are enclosed. Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that an exhaustive search has been made, or that there does not exist information more material to the examination of the present patent application. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will review art of record in all 35 U.S.C. § 120 priority documents.

☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date or before the mailing date of a first Office Action on the merits. No certification or fee is required.

☐ 2. The Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 (c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

☐ c. Attached is our check no. ____ in the amount of \$____ in payment of the fee under 37 C.F.R. § 1.17(p).

☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Applicants hereby petition that the Information Disclosure Statement be considered. Attached is our check no. _____ in the amount of \$130.00 in payment of the fee under 37 C.F.R. § 1.17(i)(1).

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

☐ b. I hereby certify that no item of information on this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

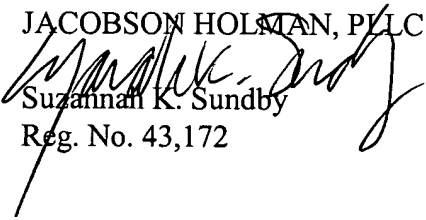
☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.

- ☒ 5. Documents 1 and 2 were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed _____, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

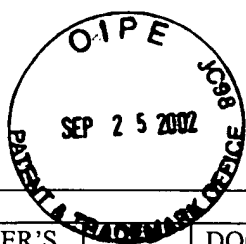
The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 210-380. A duplicate copy of this paper is enclosed.

Respectfully submitted,

JACOBSON HOLMAN, PLLC

Suzannah K. Sundby
Reg. No. 43,172

Date: 25 September 2002

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FORM PTO 1449 <u>INFORMATION DISCLOSURE STATEMENT</u> 	ATTY. DOCKET NO. P66822US0	APPLICATION NO. 09/975,020
	APPLICANT(S) MAGILL et al.	
	FILING DATE 12 October 2001	GROUP 1646

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U.S. PATENT DOCUMENTS

EXAMINER'S INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE

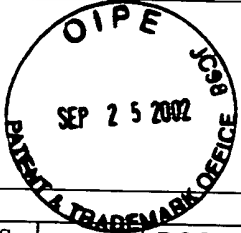
FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	WO 98/35045	08-13-98	PCT			<input type="checkbox"/> Yes <input type="checkbox"/> No
	EP 0293827 A2	05-31-88	EPO			<input type="checkbox"/> Yes <input type="checkbox"/> No

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

EXAMINER'S INITIAL			Include Author, Title, Date, Pertinent, etc.
	AA	<u>1</u>	Thomas G. EVANS et al., (1992) "Epidemiology of Visceral Leishmaniasis in Northeast Brazil" J. Infect. Dis. 166:1124-1132.
	AB	<u>1</u>	M. HO et al., (1982) "Prevalence and Disease Spectrum in a New Focus of Visceral Leishmaniasis in Kenya" Trans. Roy. Soc. Trop. Med. Hyg. 76(6):741-746.
	AC	<u>1</u>	Alan J. MAGILL et al., (1994) "Visceral Infection Due to Leishmania Tropica in a Veteran of Operation Desert Storm Who Presented 2 Years After Leaving Saudi Arabia", Clin. Infect. Dis. 19:805-806.
	AD	<u>1</u>	Alan J. MAGILL et al, (1993) "Visceral Infection Caused by Leishmania Tropica in Veterans of Operation Desert Storm", New England J. Med. 328(19):1383-1387.
	AE	<u>1</u>	Joao MONTENEGRO, (1926) "Cutaneous Reaction in Leishmaniasis", Archives of Dermatology and Syphilology, 13:187-194.
	AF	<u>1</u>	S. PAMPIGLIONE et al., (1974) "Studies on Mediterranean Leishmaniasis" Trans. Roy. Soc. Trop. Med. Hyg., 68(6) :447-453.
	AG	<u>1</u>	Steven G. REED et al., (1986) "Selection of a Skin Test Antigen for American Visceral Leishmaniasis" Am. J. trop. Med. Hyg. 35(1):79-85.
	AH	<u>1</u>	E.D. ROWTON et al., (1996) "Evaluation of Leishmania Tropica Microfluidized Skin Test Antigen in Guinea Pigs", 45 th Annual Meeting of the American Society of Tropical Medicine and Hygiene (Abstract No. 585).
	AI	<u>1</u>	J.M. STITELER, (1994) "Good Manufacturing Practices (GMP) Production of Leishmania Skin Test Antigen", 43 rd Annual Meeting of the American Society of Tropical Medicine and Hygiene (Abstract No. 179).
	AJ	<u>1</u>	J.M. STITELER, (1995) "Good Manufacturing Practices (GMP) Production of Leishmania Skin Test Antigen (LSTA)", 44 th Annual Meeting of the American Society of Tropical Medicine and Hygiene (Abstract No. 300).

EXAMINER	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

FORM PTO 1449 <u>INFORMATION DISCLOSURE STATEMENT</u> 	ATTY. DOCKET NO. P66822US0	APPLICATION NO. 09/975,020	RECEIVED SEP 26 2002 TECH CENTER 1600/2906
	APPLICANT(S) MAGILL et al.		
	FILING DATE 12 October 2001	GROUP 1646	

U.S. PATENT DOCUMENTS

EXAMINER'S INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

EXAMINER'S INITIAL			Include Author, Title, Date, Pertinent, etc.
	AK	<u>1</u>	J.M. STITELER, (1996) "Current good Manufacturing Practices (CGMP), 45 th Annual Meeting of the American Society of Tropical Medicine and Hygiene (Abstract No. 583).
	AL	<u>1</u>	J.M. STITELER, (1996) "Current Good Manufacturing Practices (CGMP) Production of a Heat-Treated Leishmania Skin Test, MFL-LSTA[R2]", 45 th Annual Meeting of the American Society of Tropical Medicine and Hygiene (Abstract No. 638).
	AM	<u>1</u>	J.M. STITELER, (1999) "Current Good Manufacturing Practices (CGMP) Production of a Heat-Treated Leishmania Skin Test, MFL-LSTA[R2], 48 th Annual Meeting of the American Society of Tropical Medicine and Hygiene (Abstract No. 738).
	AN	<u>1</u>	P. Scott, et al. (1987) "Vaccination Against Cutaneous Leishmaniasis in a Murine Model" J. Immun. 139(1):221-227.
	AO	<u>1</u>	P. M. De LUCA et al. (1999) "Evaluation of the Stability and Immunogenicity of Autoclaved and Nonautoclaved Preparations of a Vaccine Against American Tegumentary Leishmaniasis" Vaccine 17:1179-1185.
	AP	<u>1</u>	Lewis (1993) "New Disrupters Help Cell Biologists Retrieve Products" The Scientist. 7(24):18, Dec. 13, 1993.
	AQ	<u>1</u>	Microfluidics (1998) "M-110S Microfluidizer® Processor, Small Volume" Brochure.
	AR	<u>1</u>	J.M. STITELER, et al. (2000) "ODS Leishmania Skin Test, MFL-LSTA(R2)" Am. J. Trop. Med. and Hygiene 62(3):310 Abstract.
EXAMINER			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.			